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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/477,572	01/04/2000	PAUL DAVID MOONEY JR.	99-156	9431

22206 7590 12/15/2005
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EXAMINER

MENDEZ, MANUEL A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/477,572	Applicant(s) MOONEY, PAUL DAVID	
	Examiner Manuel Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 2-4 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-8 and 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>12/11/05</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/00</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Examiner's Comments

After the telephone interview conducted on December 9, 2005, the examiner performed a final search and found various patents that are considered pertinent to the prosecution of this application. In view of the new art found, the examiner will not delete claims 19-21 as agreed in during the interview.

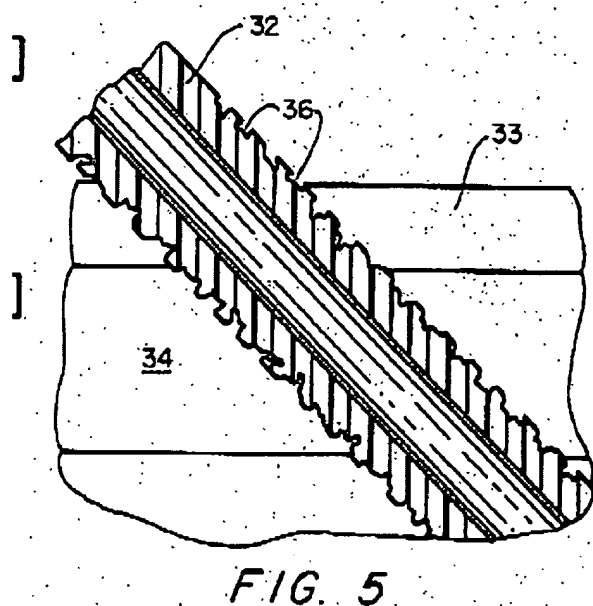
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

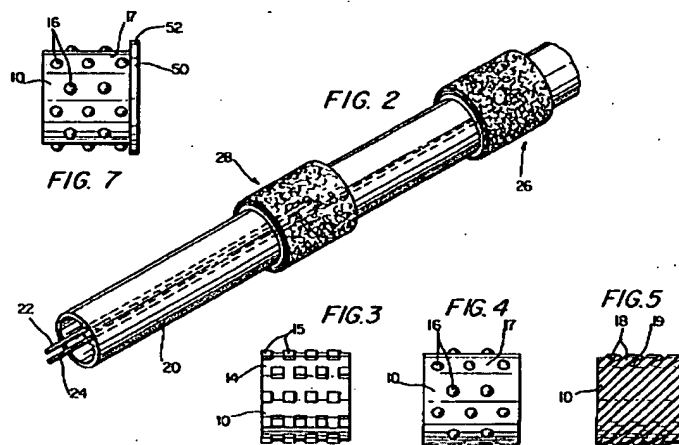
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-8, and 10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Feller, Jr., et al., in view of Kitrilakis, or Ersek, or Helfrich, or Baudino et al.**

As discussed in the previous Office Action, Feller, Jr., et al., does not disclose an interface having an exterior surface including texture thereon wherein cells grow into engagement with the texture to form a barrier against the migration of foreign matter past the interface. However, the use of an interface having an exterior surface including texture is conventional in the art as evidenced by the teachings of Kitrilakis, Ersek, Helfrich, and Baudino et al.

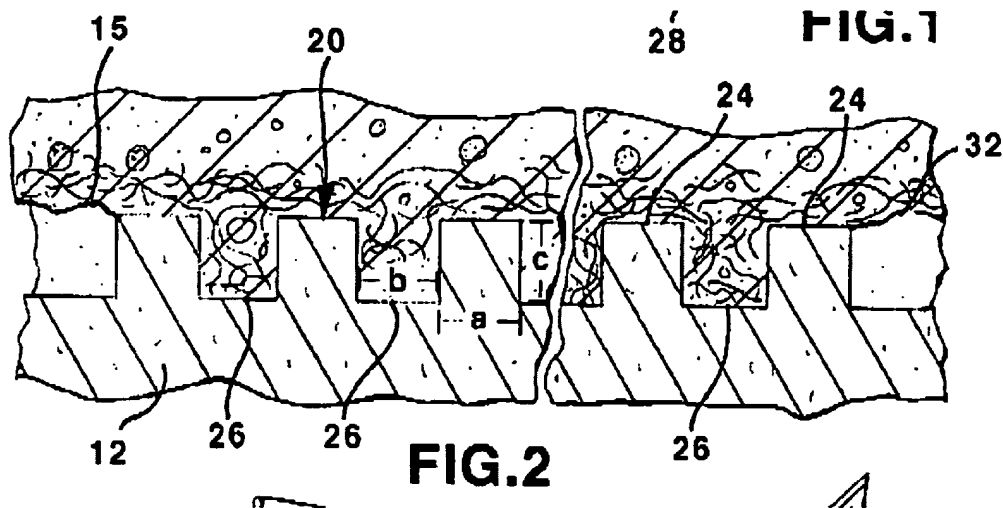


Kitrilakis discloses a surface containing microcavities for anchoring medical devices in body tissue. Ersek discloses in column 2, lines 27-34, the use of texture to attach a medical cannula to surrounding tissue. Helfrich shows in figures 2-5 and 7 below, cuffs made of woven material (texture) at one or more locations along the external surface of a catheter.



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Finally, Baudino, et al., shows in figure 2, the use of texture to attach the catheter or cannula to body tissue.



Based on the above observations, the modification of the apparatus disclosed by Feller, Jr., et al., with an interface having texture thereon wherein cells grow into engagement with the texture to form a barrier against the migration of foreign matter past the interface as taught by the cited patents would have been obvious in view of the conventionality of the enhancement. Furthermore, such enhancement would have increased the accuracy of the infusion mechanism resulting in a safer medical environment.

In relation claims 17, 18, 20 and 21, in column 3, lines 10-19, Baudino et al., discloses specific dimensions for the texture utilized in the medical device. Furthermore, it is important to recognize that the size and variety of the texture determines the effectiveness of the cell growth on the catheter surface. Accordingly, for a person of ordinary skill in the art, any specific "texture" dimensions depend on the desired rigidity between the medical device and the surrounding tissue. Moreover, it is

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the "intended use" of the catheter that determines the specific size of the peaks and valleys on the exterior surface. Therefore, based on the above observations, the disclosed dimensions in the claims in question are considered obvious.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

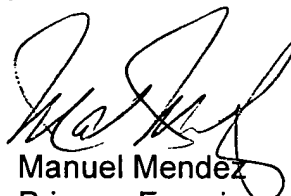
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-272-4977. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Manuel Mendez
Primary Examiner
Art Unit 3763

MM